K122044

OCT 4 2012

510(k) Summary

Applicant's Name, Address, Telephone, FAX, Contact Person
Advanced Sterilization Products, Division of Ethicon, Inc.
33 Technology Drive
Irvine, CA 92618

Contact Person
Nancy Chu
Manager, Regulatory Affairs
Tel: (949) 453-6435
Fax: (949) 789-3900

Summary Date: September 5, 2012

1. CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name:	Biological Sterilization Process Indicator
Common/Usual Name:	Biological Indicator
Product Classification:	II
Classification Regulation:	21 CFR 880.2800
Proprietary Name:	STERRAD® CYCLESURE® 24 Biological indicator

2. PREDICATE DEVICES

STERRAD® CYCLESURE® 24 Biological Indicator, K103222, 2/25/2011

3. INDICATIONS FOR USE

The STERRAD® CYCLESURE® 24 Biological Indicator (PN 14324) is intended to be used as a standard method for frequent monitoring of the following STERRAD® Sterilization Systems and Cycles:

MODEL	CYCLE
STERRAD® 100S	Standard
STERRAD® 50	Standard
STERRAD® 200	Standard
STERRAD® NX®	Standard
	Advanced
STERRAD® 100NX®	Standard
	Flex
	EXPRESS

4. DESCRIPTION OF DEVICE

The STERRAD® CYCLESURE® 24 Biological Indicator is a self-contained stand-alone biological monitor intended for the routine monitoring of the STERRAD® Sterilization Process. It consists of a glass fiber disc containing a minimum of $1x10^6$ *Geobacillus stearothermophilus* spores, a glass ampoule containing nutrient growth medium, a cap and liner closing the vial and a chemical indicator on top of the cap. The cap contains two small circular openings that allow for diffusion of hydrogen peroxide vapor into the vial. The relatively small size of the circular openings serves as a restriction to this diffusion.

5. SUMMARY OF NONCLINICAL TESTS

Both the modified and predicate devices have the same intended use, the same technological characteristics, the same operating principles, and utilize the same sterilant (hydrogen peroxide).

Testing was conducted to confirm that the STERRAD® CYCLESURE® 24 Biological Indicator performs as intended when used with the STERRRAD® Sterilization Systems. The following tests were performed:

Studies Performed	Results
Evaporation	Passed
Verification of Positive BI Color	Passed
Bacteriostasis	Passed
BI Validation in the STERRAD® Sterilization Systems (Dose Response)	Passed
Verification of Minimum Incubation Time	Passed
Growth Promotion	Passed
Spore Resistance Testing	Passed

6. DESCRIPTION OF CHANGE

The change of the material grade of the outer vial resin (relative to the predicate device, K103222) is shown in this submission to work as intended with the STERRAD® Sterilization Systems.

7. OVERALL PERFORMANCE CONCLUSIONS

Performance testing demonstrated that the modified STERRAD® CYCLESURE® 24 Biological Indicator is substantially equivalent to the predicate device (K103222) because they have the same intended use, the same technological characteristics, the same operating principles, and are exposed to the same sterilant (hydrogen peroxide).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 4 2012

Advanced Sterilization Products
Ms. Nancy Chu
Manager, Regulatory Affairs
33 Technology Drive
Irvine, California 92618

Re: K122044
Trade/Device Name: Sterrad® Cyclesure® 24 Biological Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: September 5, 2012
Received: September 6, 2012

Dear Ms. Chu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): TBD K122044

Device Name: STERRAD® CYCLESURE® 24 Biological Indicator

Indication for Use:

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STERRAD® 100NX®	Standard
	Flex
	EXPRESS

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use √ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth D. Mansini-Welsh

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K122044